American Society of
Health-System Pharmacists®
7272 Wisconsin Avenue
Bethesda, Maryland 20814
301-657-3000
Fax 301-652-8278
www.ashp.org

Statement of Kasey Thompson, Pharm.D. Director of Patient Safety, American Society of Health-System Pharmacists Before the Food and Drug Administration Public Meeting on Minimizing Medication Errors– Evaluating the Drug Naming Process, June 26, 2003

My name is Kasey Thompson, and I am the Director of Patient Safety of the American Society of Health-System Pharmacists (ASHP). ASHP is the 30,000-member national professional and scientific association that represents pharmacists who practice in hospitals (including outpatient services), health maintenance organizations, long-term care facilities, home care agencies, and other components of organized health care systems. We are grateful to the FDA for calling this public workshop to receive input on the agency's approach to minimizing medication errors through improving the drug naming process.

Section III(F) of the FDA's recent concept paper entitled "Premarketing Risk Assessment" discusses how drug sponsors can minimize medication errors. Specifically, this section states:

> Ideally, a sponsor would conduct a risk assessment to ensure that a product's proprietary name, established name, container label, carton labeling, package insert, and/or packaging do not inadvertently contribute to medication errors. For example, a sponsor could perform a medication error prevention analysis or MEPA to ... minimize the potential for an error through corrective action including renaming, relabeling or repackaging."

The concept paper goes on to state that sponsors should assess a product's name, labeling, and packaging by obtaining "first-hand information from physicians, pharmacists, nurses and consumers." This sponsor-initiated assessment would "help to minimize medication errors" and "help speed FDA's review of these issues."

At a public meeting on risk assessment last April, ASHP strongly supported inclusion of this language in any future guidance document relating to premarket risk assessment issued by the FDA, and we urge the agency to quickly implement this concept. We have been encouraging FDA to do this for a long, long time:

In September 1998, we stated at an FDA Health Professional Organization meeting that drug naming, packaging, and labeling was a critical, issue that had not been adequately addressed by the FDA, despite the fact that there had been abundant evidence that poor product design is a major contributing factor in medication errors.

At a meeting in February 1999, we stated that one solution to the problem of medication errors stemming from poor package design and nomenclature is to require real-life submissions from the pharmaceutical industry prior to drug approval, and that before the FDA approves any new

drug or biological product it should require manufacturers to document that it has rigorously tested all packaging, naming, and labeling for their potential to induce errors. This testing should be done using proven methods involving practicing pharmacists, physicians, and nurses in simulated work environments.

In May, 1999, we commented that the FDA has an obligation to quickly review and revise its procedures to eliminate medication errors that occur due to look-alike and sound-alike names, similarities in packaging, and other labeling and packaging problems. We also noted that patients should be considered the partners of health professionals in eliminating medication errors, and they should be involved in providing input into the safety design of drug product labeling. We are pleased that the FDA concept paper includes a provision for patient/consumer input.

In January 2002, in comments to the agency on its performance goals for the reauthorization of the Prescription Drug Marketing Act, we stated that "the most consistent message ASHP hears from its members is that the FDA should be doing more to assure that drugs are safe for patients," and that safety issues must be anticipated through premarket evaluation. One specific, new performance goal that we recommended was for the FDA to engage pharmacists, physicians, nurses, and human factors experts in documented failure-mode-and-effects analyses of prospective product nomenclature and labeling to minimize the opportunities for sound-alike names and look-alike packaging for causing medication errors.

In terms of the specific questions that the FDA asked participants to address for this public meeting, ASHP has the following comments:

Question 1: Are methods currently employed by sponsors and FDA appropriate for evaluating look-alike and sound-alike names?

Generally, the kinds of methods being used by the FDA could detect naming problems. Our concern is to what extent FDA staff simulates the range of "real-life," drug order situations common in hospitals and health systems.

Mobility brings together physicians, nurses, and pharmacists from different regions of the US with characteristic dialects, and from other parts of the world with primary languages other than English. Face-to-face and telephone communications are easily confused by these differences.

The methods and forms of medication order writing, capture, and transmission vary considerably among hospitals. Orders can be handwritten imbedded within progress notes or segregated on distinct order sheets that separate the drug name from indication. Orders are transmitted to the pharmacy by NCR copies and internal FAX machines which confound handwriting variations with smear and electronic artifacts.

And, let us not forget that hospital and health system patient populations are also becoming more culturally and linguistically diverse. Communications with patients (consumers) about their medications is an important component of medication error prevention.

Question 2: In studies designed to evaluate potential prescription errors: (a) What is an appropriate study design? (b) What is the appropriate size for an expert committee or for a prescription drug (written and voice recognition) study? (c) What should be the composition of a group of evaluators (e.g., what proportion of physicians, pharmacists, nurses, consumers)? (d) What are appropriate outcome measures?

Study designs should, to the extent possible, replicate common medication order situations with experientially known error vulnerabilities. Designs should include multiple detection and interception methods as appropriate for the vulnerabilities in each step of the medication-use process. Expert committees should be representative of those health professionals, especially, physicians, nurses, and pharmacists, who have essential roles in hospital and health system medication-use processes.

Question 3: What kind of information (e.g., drug name, strength, quantity, directions) should be included in verbal or handwritten prescription drug studies?

Information requirements alone are insufficient. How medication orders are communicated and the context in which they are communicated either contribute to or reduce the potential for errors. Studies should look at error potentials of propriety names alone and in the context of typical medication orders (dosage regimen) and standardized medication orders that incorporate requirements known to reduce the likelihood of misinterpretation (See ASHP Guidelines on Preventing Medication Errors with Antineoplastic Agents).

Question 5: Should there be different trade-name evaluation procedures for different classes of drugs (prescription vs. over-the-counter)?

There is no difference between prescription and non-prescription products as far as error potential for interchangeability and subsequent patient harm. ASHP would also like to emphasize the importance of name recognition for high-alert drugs (which is not an official class, but recognized in the medication safety world), such as antineoplastic and other hazardous drugs that have a very low therapeutic index, and therefore a high-probability for patient harm if an error occurs due to name confusion.

ASHP believes that the FDA is taking the right approach to this serious public health issue and appreciates this opportunity present its comments relating to the FDA's program for minimizing medication errors.

Contact Information:

Kasey Thompson, Pharm.D.
Director of Patient Safety
American Society of Health-System Pharmacists
7272 Wisconsin Ave.
Bethesda, MD 20814
301-657-3000, ext. 1270